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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,216	07/14/2003	Laurent Verard	5074A0060CPA	7018

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EXAMINER	
ROZANSKI, MICHAEL T	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,216	VERARD ET AL.	
	Examiner	Art Unit	
	Michael Rozanski	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-66* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s), (PTO/SB/08), Paper No(s)/Mail Date :11/30/06,10/17/06,3/24/06,8/16/05,8/9/04,4/23/04,10/8/03.

DETAILED ACTION

Claim Objections

1. Claim 44 is objected to because of the following informalities:

-The word "date" in the 7th line of the claim should be changed to "...data..."

Appropriate action is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/299,969. Although the conflicting claims are not identical,

they are not patentably distinct from each other because Hunter et al. substantially claims all features in obvious alternate variations and groupings. Hunter et al. claims an image guided catheter navigation system for guiding a catheter through a region of a patient, comprising an imaging device selected from a number of imaging techniques, a tracking device, a controller, and a display. Hunter et al. also claims a method comprising receiving a cyclic physiological signal and time gating the detection of the location of the catheter, as well as time gating the generation of the image.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6-8, 10-17, 20-24, 26, 30-33, 35-39, 41-48, 50-56, 58-63, 65, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin et al (US Patent No. 5,377,678).

Claims 1-4, 6, 12, 21, 22, 31, 35-37, 44, 46, 50, 52-54, 63 : Dumoulin et al. disclose a tracking system to follow the position and orientation of a device, including control means 70, imaging device 103 with support arm 101, invasive device 120 with transmit coils located thereon, display monitor 151 with display means 150, and a

tracking unit 108 (col. 2, lines 45-58; col. 3, lines 35-37). The calculated position of the invasive device is displayed by superposition of a symbol 152 on an x-ray image appearing on video monitor 151. A frame grabber 54 is used to capture an image in response to the physiological event from the x-ray system and propagates the image to superposition means 56 on the video signal supplied by frame grabber means (col. 4, lines 6-20). The system further includes a gating means used to selectively pass or block the signal and a control computer 60 that is responsive to a timing signal from master oscillator 10, which may function as a gating device (col. 3, lines 20-37; col. 4, lines 33-34). Furthermore, images of this tracking system may be obtained by a variety of different imaging modalities other than x-rays, such as MRI, ultrasound, PET, and the like (col. 7, lines 30-36).

Claims 7, 24, 33, : Dumoulin et al. disclose a tracking unit 108, which provides power to the RF transmit coil to create a dipole electromagnetic field that is detected by RF receive coils 160 (col. 3, lines 1-4).

Claims 8, 13, 16, 17, 19, 20, 23, 32, 41-43, 45, 51, 55, 56, 66: Dumoulin et al. disclose a system wherein the invasive device may be a catheter capable of delivering therapy and guided through patient vasculature, guide wire, biopsy needle, endoscope, laparoscope, or the like inserted into the body and tracked (col. 1, lines 27-31). The system further includes a gating means used to selectively pass or block the signal and a control computer 60 that is responsive to a timing signal from master oscillator 10, which may function as a gating device for providing gated delivery with stimulation of the therapy (col. 3, lines 20-37; col. 4, lines 33-34).

Claims 10, 11, 14, 15, 26-28, 30, 38, 39, 47, 48, 58-60, 65, : Dumoulin et al. disclose tracking computer 50 that communicates with control computer 60 and is capable of providing an estimated optimized site to navigate the instrument to (col. 4, lines 21-34). The tracking is performed by a number of transmit coils situated on the invasive device, wherein the signals generated by the transmit coils are detected by a number of receive coils, which are electrical sensors, placed at known locations about the subject, and are registered and displayed by the display means (col. 3, lines 38-42). A number of transmit coils 30a, 30b, 30n are capable of being placed on an ultrasonic scanner in order to track the position of the imaging device (col. 3, lines 35-42; col. 7, lines 30-36).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 5, 34, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. in view of Melkent et al (US Patent No. 6,725,080).

Claims 5, 34, and 64: Dumoulin et al. disclose tracking unit 108 that provides power to the transmit coil to create an electromagnetic, conductive field which is detected by receive coils (col. 3, lines 1-10). Dumoulin et al. do not disclose an optical-type tracking device. In the same field of endeavor, Melkent et al. teach of tracking

means that may be optical (col. 5, lines 41-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Melkent et al. to that of Dumoulin et al. in order to permit system flexibility, as well as to enhance tracking sampling via high update rates associated with an optical tracker.

7. Claims 9, 18, 25, 27-29, 40, 49, 57, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. in view of Gilboa et al (US Patent No. 6,711,429).

Claims 9 and 18: Dumoulin et al. disclose all claimed features of the current invention including invasive devices capable of delivering therapy including a catheter and a biopsy needle (col. 1, lines 28-31), except lead placement. Gilboa et al. teach of a catheter that may include a stent delivery device, a lead, and a mechanism of lead placement (col. 25, lines 46-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Gilboa et al. to that of Dumoulin et al. in order to expand the therapeutic capabilities of the system.

Claim 25: Dumoulin et al. disclose all claimed features of the current invention including an ultrasonic scanner (col. 7, lines 30-36), but do not specifically disclose the transducer operable to generate a Doppler effect. In the same field of endeavor, Gilboa et al. teach an ultrasound probe equipped with a 3D modeling algorithm capable of generating a Doppler effect for analyzing blood flow (col. 28, lines 1-6; col. 31, lines 1-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Gilboa et al. to that of Dumoulin et al. in order to

enhance to imaging capabilities of the sensor by providing a way of analyzing hemo-dynamic physiological parameters.

Claim 29, 49, 57, 61, 62: Dumoulin et al. disclose all claimed features of the current invention including invasive device 120 placed inside a patient (col. 2, lines 54-55), but do not specifically disclose that placement of a device in a coronary sinus region, wherein the physiological event is a heartbeat. In the same field of endeavor, Gilboa et al. teach of catheters placed in the coronary sinus (col. 2, lines 22-39), catheters that include lead placement (col. 25, lines 46-49), and the detected heartbeat via cardiac gating (col. 26, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Gilboa et al. to that of Dumoulin et al. in order to enhance the system to be able to perform cardiac ablation while collecting local information.

Claim 40: Dumoulin et al. disclose a tracking system 108, wherein transmit coils are attached to the end of the invasive device (col. 3, lines 35-37). Dumoulin et al. do not disclose virtual images that include a plurality of imaging planes about the distal end of the instrument including a forward imaging plane. In the same field of endeavor, Gilboa et al. teach of an imaging instrument, wherein the imaging points-of-interest are projectable among images of different planes (col. 21, lines 1-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Gilboa et al. to that of Dumoulin et al. in order to permit viewing of the distal end in cases where the relative location of the patient body and instrument is changed (col. 21, lines 37-43).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,379,302 to Kessman et al. disclose a surgical instrument navigation system 100 with ultrasound machine 105 attached to arm 110.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

MR

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER